

### **REMARKS**

Applicants thank the Examiner for the very thorough consideration given the present application. Claims 11, 14-15, 20-23 and 26 are currently pending in this application. No new matter has been added by way of the present amendment. For instance, the amendment to claim 11, as well as new claim 26, are supported by the Specification at, for example, paragraphs [0033] and [0044]. Accordingly, no new matter has been added.

In view of the amendments and remarks herein, Applicants respectfully request that the Examiner withdraw all outstanding rejections and allow the currently pending claims.

### **Issues Under 35 U.S.C. 103(a)**

Claims 11, 14-15 and 20-23 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Patel '132 in view of Nishikawa et al. (*Mesoscopic patterning of cell adhesive substrates as novel biofunctional interfaces*) (hereinafter "N1"), and Nishikawa et al. (*Fabrication of Honeycomb Film of an Amphiphilic Copolymer at the Air-Water Interface*) (hereinafter "N2"). Applicants respectfully traverse.

The Examiner asserts that Patel '132 discloses a stent comprising a stent surface and an ePTFE covering including a resin and having a porous structure formed at least on its surface, wherein the surface of the medical instrument is entirely or partially covered with the film, and wherein pores of the porous structure of the film have an average pore size of 10-100 $\mu$ m.

The Examiner acknowledges that Patel '132 fails to teach or suggest a honeycomb structure, or the claimed thickness of the film, and relies on N1 and N2 to overcome these deficiencies.

Applicants respectfully submit that the Examiner has failed to establish a *prima facie* case of obviousness. To establish a *prima facie* case of obviousness, the Examiner must make the factual determinations set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966). “[T]he examiner bears the initial burden, on review of the prior art or on any other ground, of presenting a *prima facie* case of unpatentability.” *In re Oetiker*, 977 F.2d 1443, 1445 (Fed. Cir. 1992). A patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art. *KSR Int'l Co. v Teleflex Inc.*, 82 USPQ 2d 1385 (U.S. 2007). There must be a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does. *Id.* The Supreme Court of the United States has recently held that the “teaching, suggestion, motivation test” is a valid test for obviousness, albeit one which cannot be too rigidly applied. *Id.* “[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.” *Id.* (quoting *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006)).

As amended, the present invention is directed, *inter alia*, to a medical instrument comprising a medical instrument substrate selected from the group consisting of a stent, a catheter and a medical tube, and a film including a non-biodegradable resin and an amphiphilic substance, and having a porous structure formed at least on its surface, the weight ratio of the amount of the non-biodegradable resin to the amount of the amphiphilic substance being 99:1 to 50:50, the surface of the medical instrument substrate being entirely or partially covered with the film, wherein the porous structure of the film is a honeycomb structure, pores of the porous structure of the film have an average pore size of 0.1 to 20  $\mu\text{m}$ , and the thickness of the film is

0.5 to 20 $\mu$ m (see, e.g., claim 11). The cited references fail to teach or suggest a medical instrument as claimed.

Patel '132 discloses a stent comprising a stent surface and an ePTFE covering including a resin. However, Patel '132 fails to teach or suggest an instrument as claimed, having a porous honeycomb structure, and comprising a film including a non-biodegradable resin and an amphiphilic substance. The cited secondary references fail to cure the deficiencies of Patel '132.

N1 discloses a honeycomb film formed of an amphiphilic resin. However, N1 fails to teach or suggest the use of a non-biodegradable resin, as presently claimed. Moreover, contrary to the present invention, the amphiphilic substance is the main component in the composition of N1, rather than a secondary component.

N2 discloses a honeycomb film formed of a composition that contains an amphiphilic resin (Polymer 1) and PLLA (biodegradable resin), wherein the ratio of the Polymer 1 to the PLLA is 9:1. However, as noted above, and contrary to the present invention, the PLLA in the composition of N2 is biodegradable (emphasis added). Moreover, N2 significantly differs from the present invention in terms of the amount of the amphiphilic substance used. Specifically, while the present invention utilizes the non-biodegradable resin as the main component (polymer), N2 utilizes the amphiphilic substance as the main component.

In the present invention, the film structure is not easily decomposed *in vivo* due to the use of a non-biodegradable resin as the main component. This makes it possible to maintain the cell growth inhibitory effects for a long period of time *in vivo* (see also paragraph [0033] in the Specification).

Applicants note that amphiphilic substances are unstable in liquid. As such, the film structure in prior art medical instruments may decompose *in vivo*, and the honeycomb structure may break. However, in the present invention, the amount of the amphiphilic substance is small, and further, a non-biodegradable resin is used as the main component. As a result, the honeycomb structure can be maintained, so that the cell growth inhibitory effects can be maintained for a long time *in vivo*.

Moreover, as shown in Table 1 of the present Specification, superior results are obtained when using the non-biodegradable resin of the present invention. For instance, the coefficient of variation in pore size can be reduced when 1,2-polybutadiene is used (see, e.g., new claim 26). Moreover, the growth of cancer cells can be further inhibited by using this non-biodegradable resin (see also Table 2 in the Specification).

Evidently, the cited references, alone or in combination, fail to teach or suggest a medical instrument as claimed. Accordingly, reconsideration and withdrawal of this rejection are respectfully requested.

### **Conclusion**


All of the stated grounds of rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding rejections and objections and that they be withdrawn. It is believed that a full and complete response has been made to the outstanding Office Action and, as such, the present application is in condition for allowance.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Vanessa Perez-Ramos Reg. No. 61,158 at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37.C.F.R. §§1.16 or 1.17; particularly, extension of time fees.

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Respectfully submitted,

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